

REMARKS

Since the office action made the rejection of the pending claims final, consideration of this response pursuant to the expedited procedure for response after final rejection set forth at 1059 OG 19-20 respectfully is solicited. The claims above have either been amended to clarify informalities or are rewritten from former dependent claims. These add no new matter, and require no further search or other consideration by the Examiner. A further description of the amendments follows.

Claims 1, 2, and 11-14 have been amended to clarify the steps of Claim 1 referenced so as to conform these claims to the changes in the identifying parenthetical Claim 1 step numbers as entered by amendment during prosecution. No new matter has been added. Entry of this amendment is respectfully requested.

In the Final Office Action dated August 21, 2003, the Examiner indicated that Claims 5 and 6 are allowable provided they are reproduced in independent form. In the above amendments, Applicants have rewritten Claims 5 and 6 as new Claims 16 and 17. Claim 16 rewrites Claim 5 in independent form incorporating all of the elements and limitations of its base claims. Claim 17 rewrites Claim 6 as dependent upon Claim 16. No new matter has been added, and as these claims were previously considered by the Examiner as allowable, no new search with respect to these claims is required. Consideration and entry of these claims are respectfully requested

Claim 18 rewrites Claim 15 to incorporate all the elements and limitations of the base claim. No new matter has been added.

With respect to the Examiner's rejection of this claim as failing to limit the subject matter of its base claim, Applicant's respectfully point out that the recitation of a sequential performance of steps (1) and (2) is a further limitation on the base claim, as unless the

steps of a method actually recite an order, the steps are not ordinarily construed to require one.

See Loral Fairchild Corp. v. Sony Corp., 181 F.3d 1313, 1322, 50 USPQ2d 1865, 1870 (Fed.Cir.1999). The relevant steps (1) and (2) of claim 1, to which former Claim 15 (now new claim 18) was directed, recite no order or sequence. Applicant submits, therefore, that the limitation presented in Claim 15, (now new claim 18) is a further limitation to the subject matter of Claim 1, and the objection under 37 CFR 1.75(c) is not apt. Reconsideration and withdrawal of this objection is respectfully requested.

As such, the amendments merely present the claims in a better form for allowance. No new matter has been added and, as they are directed to informalities, Applicants submit the amendments require no additional search or consideration by the Examiner. Applicants therefore request the claims be accepted and entered.

Rejection Under 35 U.S.C. § 103

The Office Action makes Final the rejection of Claims 1-4, and 7-15 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Bowen et al. (*Laboratory Hematology*, 1997, hereafter “Bowen”) in view of Gopinath et al. (*Cytometry*, 1997, hereafter “Gopinath”). Applicants continue to respectfully traverse this rejection for the reasons previously advanced and for the following additional reasons.

Applicants submit the rejection remains deficient in that the cited articles fail to account for all claimed elements and exhibit no suggestion or motivation supporting the alleged combination. Instead, the Examiner supports the rejection by speculation and conjecture. As Applicants have so often stated previously, this is insufficient to make out a *prima facie* case of obviousness.

In yet another advanced iteration of the rejection, the Examiner presently states that “Bowen et al. differ(s) from the instant invention in failing to teach staining leucocytes after the erythrocytes are removed from the hematological sample.” (Final Action of August 21, 2003, page 5). But the Examiner has previously stated in Paper 15, that “Bowen, et al., differs from the instant invention in failing to teach distinguishing eosinophils and neutrophilic cells in the granulocytic cells measured in step (3) [now step (5)] of Claim 1, which were obtained on the basis of scattered light signals and fluorescent intensity of the granulocytic cells.” (Page 5). This previous admission is not, however, present or restated by the Examiner in the Final Action. Moreover, nothing therein indicates that the Examiner has reconsidered this point. The Examiner’s silence is curious given that Applicants previously stated in its prior response that this lack of disclosure in Bowen rendered that reference fatally deficient in meeting the Applicant’s claims. (See Applicant’s April 2, 2003 response, page 5). But this argument was never addressed in the Final Action.

This is highly significant and illustrates Bowen is misapplied as a primary reference in the asserted rejection. Bowen discloses drawing a gate around a group of granulocytes in a SSC scattergram, which uses anti-CD45 fluorescence, and preparing scattergrams with respect to the granulocytes within the gate which use anti-CD 16 and anti-CD 11b fluorescence. This analysis does not allow for accurate classification and counting of immature granulocytes because of their overlap with eosinophils on the scattergram. As a result, the method of Bowen seeks left-shifted scattergram immaturity patterns (see page 296, column 2). Bowen therefore, and at the very least, does not disclose step 5 of Applicants’ Claim 1, and, as such, cannot disclose steps (6) or (7), as claimed.

The disclosure of Gopinath does not remedy this deficiency in Bowen. First of all, the Examiner improperly reads disclosure into Gopinath. The Examiner states that “According to Gopinath, use of lysed whole blood in flow cytometry allows the study of cell surface markers such as CD45, CD16, and CD11b using antibodies to CD45, CD16, and CD11b, respectively, on leucocytic cell populations without using cell purification techniques that may affect expression of these markers.” (Final Action, page 5). Gopinath, however, makes no such disclosure, indeed it describes use of anti-CD16 only in its method of distinguishing neutrophils and eosinophils in an SSC scattergram.

However, step (5) of Claim 1, reads: “distinguishing eosinophils and neutrophilic cells in the granulocytic cells obtained in step (4) *on the basis of the intensity of the fluorescence from the first fluorescence-labeled antibody and the intensity of the fluorescence from the second or third fluorescence-labeled antibody*.” Gopinath lacks this disclosure.

At the very least, neither Bowen nor Gopinath, taken either separately or together, disclose distinguishing neutrophils and eosinophils using two fluorescence based antibodies. Nor do either teach, suggest or motivate this. For this reason alone, these citations do not read on the claimed invention, nor do they render it obvious.

In addition, neither Bowen nor Gopinath disclose classifying *and* counting neutrophilic cells, as recited in the claims. Bowen is concerned with determining maturity scatterplot *patterns*, i.e., a left-shift indication of maturation delay (see Bowen, page 296), compared with specimens from normal marrow. Gopianth is directed to isolation of eosinophils. These objectives differ, and as such neither citation is concerned with *classification and counting* of neutrophils by and within maturation groups according to the claims. Even if the citations

could be combined to arrive at the claims, i.e., even if they disclosed all claimed elements (which, as demonstrated, they do not), evidence showing motivation to do so is lacking in the citations. Instead, the combination of these articles is supported only by the Examiner's hindsight reasoning, and that is insufficient to support the rejection. As such, the requirement of a *prima facie* obviousness rejection is clearly unmet, and the Applicants once again respectfully request the Examiner to reconsider and withdrawn this rejection as to all claims.

In view of the above, reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

For the reasons set forth above, entry of the amendments, reconsideration, and allowance of the claims respectfully is requested. If the Examiner has any questions regarding this paper, please contact the undersigned attorney.

By

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